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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,745	01/30/2002	Henry Yue	PF-0727 USN	6011

22428 7590 06/28/2004

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EXAMINER	
SCHNIZER, HOLLY G	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,745	YUE ET AL.	
	Examiner	Art Unit	
	Holly Schnizer	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13,15-17,19,22,25,26 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-11,13,15-17,19,22,25,26 and 28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7, 9, 11, 16, 17, and 19, drawn to a polypeptide, the polynucleotide encoding the polypeptide, a host cell, method of making the polypeptide, and method of using the polypeptide to screen for agonists.

Group II, claim(s) 8, drawn to a transgenic animal.

Group III, claim(s) 10, drawn to an antibody.

Group IV, claim(s) 13 and 28, drawn to a hybridization assay.

Group V, claim(s) 15, drawn to a PCR amplification assay.

Group VI, claim(s) 22, drawn to a method of screening for an antagonist.

Group VII, claim(s) 25, drawn to a protein binding assay.

Group VIII, claim(s) 26, drawn to a method of screening for a compound that modulates the protein activity

Group IX, claim(s) 27, drawn to a method for screening for compounds that modulate protein expression using a DNA expression assay.

Group X, claim(s) 28, drawn to a method of assessing toxicity of a compound by a DNA hybridization assay.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Pursuant to 37 C.F.R. § 1.475(d), the ISA/US considers that where multiple products

and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention (Group I) comprises the first recited product; a polypeptide, a polynucleotide that encodes the polypeptide, methods of making the polypeptide and the first recited method of using the polypeptide to screen for agonists. Further pursuant to 37 C.F.R. § 1.475(d), the ISA/US considers that any feature which the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT Rule 13.2 and that each of such products and methods accordingly defines a separate invention.

The special technical feature of Group I is considered to a polypeptide of the recited sequence.

The special technical feature of Group II is considered to be a transgenic animal.

The special technical feature of Group III is considered to be an antibody that recognizes a polypeptide of a specific sequence.

The special technical feature of Group IV is considered to be a method of detecting a polynucleotide of specific sequence with a hybridization assay.

The special technical feature of Group V is considered to be a PCR assay.

The special technical feature of Group VI is considered to be a method of screening for antagonists of a polypeptide of specific sequence.

The special technical feature of Group VII is considered to be a protein binding assay.

The special technical feature of Group VIII is considered to be a method for screening a compound that modulates the activity of a polypeptide of a specific sequence.

The special technical feature of Group IX is considered to be a DNA expression assay.

The special technical feature of Group X is considered to be a method of assessing the toxicity of a compound by DNA hybridization assay.

Accordingly, Groups I-X are not so linked by the same or corresponding special technical feature as to form a single general inventive concept.

Additional Restriction to a Single Polypeptide, Polynucleotide, or Antibody

The claims of Groups I-X are drawn to a multitude of polypeptides (SEQ ID NOs:1-27), polynucleotides encoding the polypeptides (SEQ ID NOs: 28-54), antibodies thereto, and methods of using these compounds. The inventions of each of these polypeptide sequences listed above do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The polypeptides of SEQ ID NOs: 1-27 and the polynucleotides that encode them have different structural features (sequences) and therefore functional features. And, there is no apparent shared common core structure and no apparent shared art recognized function. For example, the polypeptide sequence of SEQ ID NO:1 is similar to a serpin sequence, the polypeptide sequence of SEQ ID NO:2 is similar to ubiquitin carboxyl-terminal hydroxylase sequence, the polypeptide sequence of SEQ ID NO: 8 is similar to a zinc binding metalloproteinase sequence, and the polypeptide sequence of SEQ ID NO:16 is similar to kunitz type protease inhibitors sequence. Thus, each of the sequences appears to encode a unique function. Moreover, each of the sequences is unique and there is no common core structure that categorizes the sequences into a single family.

Therefore, upon election of one of Groups I-X, Applicant is required additionally to elect a single polypeptide, polynucleotide (encoding a single polypeptide) or antibody (specific for a single polypeptide sequence) depending on the inventive Group which is

elected and including the method groups. This requirement is not to be construed as a requirement for an election of species, since each of the compounds recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

A telephone call was made to Michele Simkin on June 21, 2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (571) 272-0958. The examiner can normally be reached on Monday through Wednesday from 8 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Holly Schnizer
June 14, 2004

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